CPME/AD/Brd/251002/31/EN/fr

At its Board meeting, Salzburg, October 25th, 2002, the CPME adopted the following policy : "**CPME statement on the document from the Commission "Detailed Guidelines of the principles of good clinical practice in the conduct in the EU of clinical trials on medicinal products for human use**
(CPME 2002/115 Final EN/fr)

Policy statement of the CPME on the Commission document "Detailed Guidelines on the principles of good clinical practice in the conduct in the EU of clinical trials on medicinal products for human use."

It is with interest that the CPME has learned of the draft entitled "Detailed Guidelines on the principles of good clinical practice in the conduct in the EU of clinical trials on medicinal products for human use."

These good practice recommendations have been proposed to supplement Directive 2001/20/EC. The CPME is pleased at the attention that the Commission has paid to the drafting and publication of good practice recommendations in an area that European doctors consider as particularly important. In particular, anything concerning patient information, in clinical practice as well as in clinical trials, has the CPME's full attention.

Nevertheless, the CPME has the following comments.

- **Section 4.1**

Version 1996 of the Declaration of Helsinki is referred to in the text, as in Directive 2001/20/EC, whereas the World Medical Association adopted a revised version of this declaration in October 2000. The CPME considers that this new version constitutes important progress, although certain points could have been examined critically. Among these, the use of a placebo in clinical trials (Section 29 of the revised Declaration of Helsinki), has subsequently been clarified in a note of clarification which has allowed satisfactory response to all the objections raised. Under these circumstances, the CPME is surprised that the Commission continues to refer, in the documents it drafts, to an old version of the Declaration of Helsinki.

- **Section 4.9**

Particular precautions must be put in place for the participation in a clinical trial for persons who are, temporarily or on a long-term basis, vulnerable or incapacitated, to receive information and give consent. The proposed recourse to the consent of a “legal representative” only raises new problems. On the one hand, as is moreover emphasised in the Commission document, there is no single definition of a legal representative in the different legislations of the Member States, and on the other, in by far the majority of cases, an adult person does not have a legal representative in the legal sense which is attempted to be given to this term. We must point out that, during a clinical trial, it is always a delicate situation when the person who is directly concerned is, temporarily or on a long-term basis, incapable of giving informed consent and this responsibility needs to transferred to a third party. The CPME therefore recommends that the Commission takes much greater account of this difficulty and amends its recommendations in this matter.

- **Section 4.10**

The CPME considers that this recommendation is insufficient with regard to ethical requirements relating to conducting clinical trials. No data from biomedical research on humans must be lost or even put aside or made inaccessible. This fundamentally concerns the issue of the respect the person who is willing to be involved in the research. An obligation to publish would therefore be unrealistic. Directive 2001/20/EC provides for the establishment of a database of clinical trials, this database would naturally be private – for reasons of industrial data protection. The CPME emphasises the importance and urgency of an effective set-up of this database.